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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,477	12/17/2003	Donald K. Jones	CRD5046USANP	8210

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EXAMINER	
OSINSKI, BRADLEY JAMES	
ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
01/12/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/738,477	JONES ET AL.	
	Examiner	Art Unit	
	BRADLEY J. OSINSKI	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al (US 2002/0143348) in view of Pinchuk et al (2002/0107330).

a. Wallace et al teaches a medical device composed of a support member 2 used as an embolic device (title) which is covered in a polymer that is partly solvated by a liquid agent, after which the surface of the support member 2 is exposed to bodily fluids. *"In certain embodiments, the material (e.g. polymer) to be solvated is coated onto the surface of the device(s)…" (Paragraph 43)* and *"…the liquid agent is capable of solvating polymeric material of the device." (Paragraph 23).* Delivery is done via a catheter, *"…a large catheter is introduced through an entry site in the vasculature" (Paragraph 46).* The tip of the catheter is advanced to the selected site, *"Once the distal end of the catheter is positioned at the site, often by locating its distal end through the use of a radiopaque marker material and fluoroscopy, the catheter is cleared." (Paragraph 46).* The device is then delivered through the catheter, "The device is advanced past the distal end of the catheter and positioned or extruded precisely at the desired treatment site.

" (Paragraph 46), after which the liquid agent is delivered, *"The liquid agent is preferably infused after extrusion…" (Paragraph 46)*

While Wallace et al substantially discloses the apparatus as claimed, it does not disclose a bioactive agent disposed between the support member and the barrier nor does he teach the polymer is specifically a barrier. Pinchuk et al, which is partly drawn to aneurysm fillers, "Preferred medical devices for use in conjunction with the present invention include… composites for aneurysm fillers" (Paragraph 180), does teach a barrier layer of polymers, "In some instances, it may be desirable to temporarily enclose the therapeutic-agent-loaded copolymer to prevent release before the medical device reaches its ultimate placement site." (Paragraph 183) and "It also may be useful to coat the copolymer of the present invention (which may or may not contain a therapeutic agent) with an additional polymer layer (which may or may not contain a therapeutic agent). This layer may serve, for example, as a boundary layer to retard diffusion of the therapeutic agent and prevent a burst phenomenon whereby much of the agent is released immediately upon exposure of the device or device portion to the implant site." (Paragraph 204) The polymers taught by Wallace et al such as polyvinylpyrrolidone, polyesters, polyethylene, etc (paragraph 30) are also many the polymers taught by Pinchuk et al. (Paragraph 205) Wallace et al does teach, *"The devices, assemblies, and methods described herein may also include one or more bioactive materials… for example a thrombotic agent… " (Paragraph 39, emphasis added)* Therefore it would have been obvious to one of ordinary skill in

the art at the time the invention was made to form a medical device of Wallace et al such that a thrombotic agent as taught by Pinchuk is disposed between a polymer coating and support member because: a) as noted above, Wallace et al teaches the device may include a thrombotic agent, and b) Pinchuk suggests coating with a polymer identical to the polymers of Wallace et al to "…prevent release before the medical device reaches its ultimate placement site." (Paragraph 183)

Response to Arguments

2. Applicant's arguments filed 4/27/2009 have been fully considered but they are not persuasive. Paragraph 183 is again cited as specifically preventing release of the therapeutic agent before the medical device reaches its ultimate placement site. Thus while in certain incarnations the prior art does teach automatically dissolving outer coatings, in other incarnations including the one cited, it does not.

3. Applicant's amendments are not found to define over the prior art of record. Wallace is drawn to an embolic device (title). Wallace also discusses partially dissolving the polymeric material (Paragraphs 15, 23 and 40). Wallace discloses the embolic device as being metals, polymers or combinations thereof (Paragraph 28) not just liquids. Thus the metal or polymer portion of Wallace could be coated with the bioactive agent of Pinchuk as mentioned in the end of the abstract of Pinchuk.

4. Applicant argues that Pinchuk discloses only a sheath covering, not a barrier to be dissolved. As previously cited, Pinchuk discloses a polymer layer (paragraph 205)

and, as also previously cited, includes the same polymers in its list (paragraph 205) as does Wallace.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY J. OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley J Osinski/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767